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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
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09/374,142 08/11/99 LIN

H P07-42146

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| EXAMINER |
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HM12/0829

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| FIELDS. I | |
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| ART UNIT | PAPER NUMBER |

1645

DATE MAILED:

08/29/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/374,142

Applicant(s)

LIN ET AL.

Examiner

Iesha P Fields

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum-statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) ____ is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 12-30 and 56-58 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claims ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on 11 August 1999 is: a) ☐ approved b) ☒ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892) 18) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) ☐ Notice of Informal Patent Application (PTO-152)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____ 20) ☐ Other: ____.

DETAILED ACTION

Applicant's election without traverse of Group II, claims 12-30 and claims 56-66 (Paper Number 5) received April 30, 2001 is acknowledged. Additionally, applicant's have elected a macrolide compound, erythromycin, 5-HT receptor antagonist, and alosetron as the species within Group II for examination (Paper No 10). Consequently, claims 12-30 and claims 56-66 are pending in the instant application and the claims within this group will only be examined to the extent of the elected species.

Drawings

This application has been filed with informal drawings which are acceptable for examination purposes only. Formal drawings will be required when the application is allowed.

Claim Rejections - 35 USC § 112

- 1. Claims 12-30 and 56-58 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.**

A) The claims are vague and indefinite in recitation of "SIBO". One skilled in the art would be unable to determine the meets and bounds of such a limitation. For example, what is "SIBO"? Without a clear definition as to what is meant by SIBO one of skill in the art would be unable to replicate the claims.

B) The claims are further vague and indefinite in recitation of whereby the symptoms are "improved". One skilled in the art would be unable to determine the meets and bounds of such a limitation. For example, what constitutes as an "improvement"? Without a clear definition as to what constitutes as an improvement one of skill in the art would be unable to replicate the claims.

C) Claims 12 and 27 are vague and indefinite in recitation of "substantially simultaneously". One skilled in the art would be unable to determine the meets and bounds of such a limitation. Without a clear definition as to what is meant by substantially simultaneously one of skill in the art would be unable to replicate the claims.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 12-30 and 56-58 are rejected under 35 U.S.C. 102 (b) as being anticipated by McCann et al., Sandborn et al., and Becker et al.

The claims are drawn to methods of treating irritable bowel syndrome (IBS).

McCann et al. (US Patent 5,599,795) disclose a method of treating irritable bowel syndrome comprising detecting the presence of intestine bacterial overgrowth in a human subject with Crohn's Disease. McCann et al. further disclose a method of treating Bifidobacterium with antibiotics (See Entire Document).

Sandborn (US Patent 5,691,343) disclose a method of treating irritable bowel syndrome. Sandborn further disclose a method of treating irritable bowel syndrome wherein the antimicrobial agent is a 5-aminosalicylate compound (See Entire Document; especially Detailed Description of the Invention).

Becker et al. (US Patent 5,612,366) disclose a method of treating irritable bowel syndrome by administering a prokinetic agent wherein the agent is a 5-HT receptor antagonist (See Entire Document).

Status of the Claims

3. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Iesha P Fields whose telephone number is (703) 605-1208. The examiner can normally be reached on 7am-3:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (703) 308-3909. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Iesha Fields

August 24, 2001



MARK NAVARRO
PRIMARY EXAMINER